MAR 1 8 2014

ASAHI INTECC CO.,LTD.
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510(k) Summary
[as required by 21 CFR 807.92(c)]

ASAHI PTCA Guide Wire ASAHI Gaia

510(k) K133865

APPLICANT	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024 Japan
OFFICIAL CORRESPONDENT	Yoshi Terai President, CEO Asahi Intecc USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252 FAX (949) 756-8165 e-mail: asahi.ra-fda@asahi-intecc.com
DEVICE NAME:	ASAHI PTCA Guide Wire ASAHI Gaia
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter, Guide, Wire
PRODUCT CODE	DQX- Catheter Guide Wire
PREDICATE DEVICES:	K101986 - ASAHI UltimateBros3 PTCA Guide Wire K100578 - ASAHI SION PTCA Guide Wire K122469 - ASAHI SION J PTCA Guide Wire K041531 - ASAHI PTCA Guide Wire Confianza Pro K043422 - ASAHI PTCA Guide Wire, J Shape series (ASAHI Confianza Pro J)
DATE PREPARED:	March 7, 2014

INTENDED USE:

ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

DESCRIPTION:

The product, ASAHI PTCA Guide Wire ASAHI Gaia (hereafter ASAHI Gaia), is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

The basic structure of ASAHI Gaia consists of a tapered core wire and coils. There are currently three models of the ASAHI Gaia:

- ASAHI Gaia First
- ASAHI Gaia Second
- ASAHI Gaia Third

Each of these models share similar design characteristics and have the same maximum outside diameter. The models differ in the distal diameter.

The ASAHI Gaia consists of a tapered core wire and two distal coils: an inner and outer coil. The outer coil is radiopaque so as to be easily confirmed of its position under radioscopy. The distal part of the ASAHI Gaia is tapered. The distal tip of the ASAHI Gaia is available straight or pre-shaped.

In addition, coatings are applied on the surface of the product. The distal part is coated with hydrophilic polymer, and the proximal part is coated with PTFE.

COMPARISON TO PREDICATE DEVICES:

Comparisons of the ASAHI PTCA Guide Wire ASAHI Gaia and predicate devices show that the technological characteristics of the ASAHI Gaia such as the intended use, components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate devices. The Gaia guidewire combines the torqueability and crossability of two predicate devices, therefore allowing for more choice for the physician.

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI Gaia to determine substantial equivalence. The following testing assessments were performed:

- Tensile Strength
- Torque Strength

- Torqueablity
- Tip Flexibility
- Coating Adhesion/Integrity
- Catheter Compatibility
- Coating Integrity and Acute Particulate Characterization

BIOCOMPATIBILITY:

The ASAHI Gaia was compared to the predicate devices. Based on similarities of the materials used in the subject device to its predicates, the biocompatibility of the ASAHI Gaia was verified to be the same as those of predicates.

CONCLUSION:

The ASAHI Gaia has the same intended use and similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended, and is as safe and effective as its predicates.

Therefore, the ASAHI PTCA Guide Wire is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2014

Asahi Intecc USA Inc.
c/o Semih Oktay, PhD
President
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K133865
Trade/Device Name: ASAHI PTCA Guide Wire – ASAHI Gaia
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 18, 2013
Received: December 19, 2013

Dear Dr. Oktay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133865

Device Name: ASAHI PTCA Guide Wire
ASAHI Gaia

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)